Cover Sheet

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ID:D2898P Improving Quality of Life for Veterans With Stroke and Psychological Distress

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-43730
Status: Approved
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Section Aa: Title & PI

A1. Main Title

IMPROVING QUALITY OF LIFE FOR VETERANS WITH STROKE AND PSYCHOLOGICAL DISTRESS

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: VA CENTRAL OFFICE, RR&D

A6a. Institution(s) where work will be performed:

Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?

No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?

No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in an journal belonging to the ICMJE. Registration is not required.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Veterans with stroke often experience comorbid psychological distress (i.e., depression and anxiety). A recent meta-analysis and systematic review indicates depression is present in 33%, and anxiety is present in 24%, of patients with recent stroke. Untreated or poorly managed psychological distress decreases stroke outcomes for physical functioning (PF), social role functioning (SRF) and quality of life (QoL). PF is often characterized as engagement in activities of daily living (i.e. bathing and grooming) whereas SRF refers to participation in valued social roles, including employee, student, family member, friend, teammate, etc. Impairments in PF and SRF are associated with poor QoL poststroke.

Stroke self-management treatment can improve disability, confidence in recovery, and QOL. Veterans with comorbid stroke and psychological distress have suboptimal outcomes. They are less adherent to PF and physical activity self-management behaviors that promote mobility and experience social isolation; limit interactions with family, friends and community members; and disconnect from social networks. Few self-management treatments address or treat comorbid psychological distress. Enhanced behavioral self-management programs addressing disease-specific self-management and psychological distress have evidenced positive physical, social and QoL outcomes in Veterans with similar neurological conditions. There has yet to be such a treatment for Veterans with stroke and psychological distress. The Co-I, Dr. Anderson, developed the Self-management TO Prevent Stroke using Video teleconferencing (VSTOP-II) intervention that decreases behaviors that are risk factors for stroke and improves stroke health outcomes. The PI, Dr. Evans, developed a cognitive-behavioral treatment that targets healthy eating and physical activity health behaviors and psychological distress management, Enhancing Psychological Distress Coping (EPiC), which demonstrated improvements in psychological distress and QoL. The 2 programs will be combined to develop a single, behavioral stroke self-management treatment that addresses both stroke risk reduction and psychological distress. The intervention is intended to help Veterans practice health behaviors that reduce risk of a second stroke and is titled "I'm Whole".

Section D: Purpose and Objectives

The overall goal of this study is to develop, refine, and pilot the I¿m Whole treatment for Veterans with stroke and comorbid psychological distress. This project will also gather preliminary data on the effects of I¿m Whole on QoL, PF (activities of daily living and physical activity), SRF, psychological distress and satisfaction with I¿m Whole.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Asymptomatic patients with chronic conditions, healthy

Which if any of the following vulnerable populations will be recruited as subjects?
Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

We will recruit male and female Veterans with mild to moderate symptoms of anxiety and depression . Participants who have poorly controlled mental illness that prevent capacity to provide consent will be excluded from the study. Participants who are unable to provide informed consent or who demonstrate cognitive limitations as evidenced by a score of 3> on a cognitive screened will be excluded from the study. We will use the teach back method of ensuring the Veteran understands the purpose, procedures, benefits and risks of participation of the study to ensure they understand, are able to provide proper consent and to prevent any coercion. Veterans who are unable to successfully repeat back the study information will be excluded. We will also consent individuals after they have discharged from the hospital and have been back in their home setting to prevent obtaining consent from anyone under duress associated with an acute care setting.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

I¿m Whole is a 6 session behavioral treatment that addresses psychological distress and stroke self-management behaviors that will be delivered via VT in the home. The treatment will be delivered weekly over 6 weeks. One module will be provided each session. The sessions will last approximately 30-45 minutes.The first module will combine the VSTOP-II stroke self-management education regarding stroke risk factors and EPiC psychoeducation on how comorbid psychological distress can create barriers to engaging in stroke self-management behaviors. Clinicians will work with each Veteran to establish individualized plans for psychological distress management and strategies for practicing tailored PF, physical activity and SRF behaviors in line with the Veteran¿s values. Progress towards the Veteran¿s tailored PF, physical activity and SRF behaviors will be reviewed, and psychological distress barriers will be discussed in future modules. Modules 2-5 will be electives that provide cognitive behavioral treatment (CBT) based behavioral activation, social-support, cognitive-restructuring, thought-stopping, deep-breathing, and problem-solving skills for improving psychological distress-related barriers to practicing established PF, physical activity and SRF behaviors. Module 6 consists of a relapse prevention plan for continued management of psychological distress. Homework and tracking logs will be provided at the end of each session. The Co-I, Dr. Villareal, will provide feedback during the development and refinement stages regarding creating tailored PF and physical activity strategies for participants. The Co-I, Dr. Sander, will provide feedback in the development and refinement stages regarding client-centered strategies for reintegrating into family and community roles and activities poststroke. A clinician manual and patient workbook will be developed.

In phase I: The PI will work with the study team to combine the EPIC and VSTOP treatments into one cohesive treatment called IM WHOLE. No Veterans will be involved in this phase.

In Phase II: The PI will pilot I¿m Whole by treating 5 Veterans suffering from stroke and comorbid psychological distress. Five Veterans with stroke and comorbid psychological distress will be recruited from the stroke acute care unit, rehabilitation unit, and outpatient stroke follow-up clinic. Qualitative interviews asking the Veterans opinion regarding the treatment content and delivery method will be administered at the end of the final session.

In phase III:Interested Veterans will be randomized to I¿m Whole (n=15) or usual care plus education (UC+E) (n=15), respectively. Veterans in the UC+E group will receive standard acute care, rehabilitation unit or

outpatient follow-up clinic stroke treatment provided at the MEDVAMC. The standard of care for these patients consists of appointments in the outpatient stroke follow-up clinic, medication management for comorbid chronic diseases, and general physical rehabilitation exercises. To account for additional treatment contact provided to participants in I¿m Whole, UC+E will also receive 6 brief telephone calls with information regarding unrelated health topics (e.g., breast, colon, rectal, esophageal, skin and testicular cancer treatment and prevention). We will track the number of patients screened, number and percent of patients eligible, number randomized, number and percent completing treatments, and number and percent completing subsequent follow-up assessments following treatment completion. Veterans in I¿m Whole will complete the same qualitative interviews described in phase II.

Inclusion Criteria:

Inclusion for Phase II and Phase III:1) a documented history of stroke and/or transient ischemic attack within the last 30 days, 2) a modified Rankin score of > 3, 3) regular access to a computer or tablet with internet and a camera, 4) ability to give appropriate informed consent, 5) score > 5 on a measure of depression (Patient Health Questionnaire [PHQ-8]) and/or >17 on a measure of anxiety (Generalized Anxiety Disorder-7 [GAD-7]) assessments, 6) ability to ambulate with or without assistance of a cane or walker.

Exclusion Criteria:

Exclusion Criteria for Phase II and Phase III: 1) cognitive impairment, as evidenced by a score of >3 on a brief cognitive screener; 2) documented diagnosis of psychotic disorder or schizophrenia; 3) documented severe depression, anxiety (based on PHQ-8 or GAD-7 score of > 20), or hospitalization for psychiatric illness within the past 30 days.

F2. Procedure

Phase I: The PI will merge stroke self-management and psychological distress treatment modules from their established EPiC and VSTOP-II programs. The first module will combine the VSTOP-II stroke self-management education regarding stroke risk factors and EPiC psychoeducation on how comorbid psychological distress can create barriers to engaging in stroke self-management behaviors. Clinicians will work with each Veteran to establish individualized plans for psychological distress management and strategies for practicing tailored PF, physical activity and SRF behaviors in line with the Veteran¿s values. Progress towards the Veteran¿s tailored PF, physical activity and SRF behaviors will be reviewed, and psychological distress barriers will be discussed in future modules. Modules 2-5 will be electives that provide CBT-based behavioral activation, social-support, cognitive-restructuring, thought-stopping, deep-breathing, and problem-solving skills for improving psychological distress-related barriers to practicing established PF, physical activity and SRF behaviors. Module 6 consists of a relapse prevention plan for continued management of psychological distress. Homework and tracking logs will be provided at the end of each session. Dr. Villareal will provide feedback during the development and refinement stages regarding creating tailored PF and physical activity strategies for participants. Dr. Sander will provide feedback in the development and refinement stages regarding client-centered strategies for reintegrating into family and community roles and activities poststroke. The treatment will consist of 6 sessions over 6 weeks and will be delivered to Veterans in their homes, using VT technology. A clinician manual and patient workbook will be developed. There will be no Veteran involvement at this phase.

In Phase II: The PI will pilot I¿m Whole by treating 5 Veterans suffering from stroke and comorbid psychological distress. Five Veterans with stroke and comorbid psychological distress will be recruited from the stroke acute care unit, rehabilitation unit, and outpatient stroke follow-up clinic. The participants will receive each of the I'm Whole sessions using VT in the home. Sessions will be delivered weekly over 6 weeks. Clinicians will work with the Veteran to establish goals in the first session that will be reviewed through the remaining sessions. Qualitative interviews asking the Veterans opinion regarding the treatment content and delivery method will be administered at the end of the final session.

The barriers to receiving the intervention via VT and acceptability of the intervention content and procedures will be assessed informally after each session, and responses will be reviewed at weekly team meetings to address any unanticipated results and make needed immediate changes to the intervention. A semi-structured interview will occur with each Veteran post-treatment, conducted by the RA trained by Co-I Martin, an expert in qualitative methods. Interviews will occur by phone and include open-ended questions regarding recruitment; engagement and retention strategies; assessment procedures; participant burden; redundancy and length and frequency of treatment; effectiveness, usefulness of I¿m Whole content, and perceived benefits and barriers to receiving the sessions via VT to the Veteran¿s home. Detailed notes will be taken during interviews, which will also be audio recorded and transcribed for analysis. Rapid analysis is a systematic and rigorous process of condensing qualitative data to quickly identify key findings to inform study progress (i.e., refine and modify I¿m Whole content, delivery methods and treatment procedures). The information from the transcribed notes and feedback received in weekly meetings will be used to modify the IM WHOLE treatment.

Phase II and Phase III: Screening and Recruitment Procedures. We will recruit men and women Veteran stroke patients of all races and ethnicities with depression and anxiety symptoms who are being treated in the stroke acute care inpatient unit, rehabilitation unit, or outpatient stroke follow-up clinic at the Michael E. DeBakey VA Medical Center (MEDVAMC). The MEDVAMC treats over 310 Veterans with stroke each year, of which approximately 93 (33%) have comorbid psychological distress. We have successfully recruited Veteran stroke patients in our previous stroke studies. The research assistant (RA) will approach potential participants at bedside in the acute or rehabilitation unit or during the first follow-up visit after admission from the stroke acute care unit. Veterans interested in the study will be screened for eligibility via their electronic medical records (EMR) to see if they meet preliminary study inclusion/exclusion criteria (listed above). Those who meet the eligibility criteria will receive a follow up session. in their home or at the MEDVAMC to be administered the screening measurements listed above. If participants via EMR review or baseline assessments: 1) do not demonstrate or show evidenced of a cognitive impairment, as evidenced by a score of >3 on a brief cognitive screener; 2) have a documented diagnosis of psychotic disorder or schizophrenia; 3) score in the severe range for depression, or anxiety (based on PHQ-8 or GAD-7 score of > 20), or have a documented or self-reported hospitalization for psychiatric illness within the past 30 days, they will be invited to participate in the study. They will be provided instructions regarding using VTEL to conduct their sessions, given a I¿M WHOLE workbook and scheduled a time for first session with the study clinician. A note will be placed in the electronic medical records (EMR)s documenting the visit. Participants who do not meet the criteria will be immediately notified of their ineligibility. A note will be placed in the EMR documenting why they were not eligible. Their primary care provider will be signed to the note for follow up discussion regarding possible referrals or additional services needed for the Veteran. The Veteran will also be provided a list of community based psychiatric and medical resources.

Phase II and Phase III: Treatment Procedures and Development-- Sessions will be conducted by 1 clinician with master¿s-level training in health education, counseling or social work and expertise in CBT, psychological distress treatment, and/or chronic disease management. The clinician will conduct the sessions from the MEDVAMC using VA Video Connect VT to the Veterans in their homes. The MEDVAMC frequently uses VT for clinical treatment and research and has established VT programs and equipment that is VHA approved and readily available.

Assessment Procedures. Each participant in phase II and phase III will receive 20.00 for each assessment they complete (0/6/12 weeks). Assessments will be conducted by an Independent Evaluator (IE). We estimate that each assessment will take about 30 to 40 minutes. If scores on the psychological distress measure worsen (e.g., 20% or more increase), the PI will be notified and participants referred to mental health treatment within the MEDVAMC or the community.

Phase III: This group will consist of the treatment (I'm Whole group) and usual care group will receive the standard of care. The standard of care for these patients consists of appointments in the outpatient stroke follow-up clinic, medication management for comorbid chronic diseases, and general physical rehabilitation exercises. To account for additional treatment contact provided to participants in I¿m Whole, UC+E will also receive 6 brief telephone calls with information regarding unrelated health topics (e.g., breast, colon, rectal, esophageal, skin and testicular cancer treatment and prevention).

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 50 Worldwide: 50

Please indicate why you chose the sample size proposed:

Phase I: does not involved participants. We plan to recruit 5 participants for phase II and 30 participants for phase III. To account for a 40% drop out rate the PI evidenced in a prior studying using Video telehealth, we will over recruit for phase II and phase III. Recruitment feasibility of approximately 6 subjects per month is based on the number of participants from Dr. Anderson¿s VSTOP study who also had comorbid psychological distress. The study is underpowered to show clinically meaningful efficacy of I¿m Whole when compared to usual care.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

We hypothesize that, at 12 weeks posttreatment, Veterans randomized to I¿m Whole will show greater improvements in the primary outcome (QoL) and secondary outcomes (PF, physical activity, SRF and psychological distress). On the basis of retention rates for VSTOP trials using VT, we anticipate a 20% loss-to-follow-up rate at 12 weeks post-treatment. Initial analyses will be intention-to-treat. Analyses will be repeated using the observed data (completer analyses). We will run linear regression models. The model for each outcome will include treatment, time (baseline, posttreatment, and 12 weeks post-treatment) and treatment-by-time interaction. Significant interaction will indicate that the intervention groups showed differential improvement over time. We will use SAS PROC MI and PROC MIANALYZE to impute missing data and conduct analyses. Key demographic and clinical variables (e.g., age, gender, stroke, psychological symptom severity and psychotropic medication use) will be described for each group as recommended by the CONSORT statement for RCTs. We will calculate the effect size, d, at post-treatment and at 12 weeks posttreatment, using mean values from the estimated means and standard errors from the linear model analyses of the imputed datasets.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The study will present minimal risks or discomforts. Participants will be asked if they have any psychological distress that may prevented them from fully participating in their stroke self-management treatment. Participants may become mildly uncomfortable with disclosing their psychological distress level and symptoms. However, participants will be reminded that they can discontinue their participation at any time if they feel uncomfortable or feel like their symptoms are getting worse as a result of the treatment. The PI is a licensed psychologist who is able to provide any additional support, symptom assessment, and/or referrals for psychological services that may be needed.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Participants can gain a better understanding of their barriers to healthy eating, physical activity, physical mobility, social engagement, and medication adherence . Understanding and implementing changes to overcome these barriers can lead to improved stroke self-management, decreased stroke risk and improve overall health outcomes.

Describe potential benefit(s) to society of the planned work.

Psychological distress is common among patients who have had a stroke. Increased psychological distress is a predictor of poor mobility and quality of life outcomes post stroke. Thus, it is essential to understand psychological distress barriers to healthy engagement in stroke self-management behaviors. This information should be used to incorporate psychological distress treatment into evidenced based stroke self-management interventions to improve health outcomes among persons at high risk for secondary stroke and related chronic disease. Successful findings can lead to the development and implementation of a comprehensive treatment that addresses stroke self-management and psychological distress concurrently. This can have widespread public health implications given the high prevalence rate of stroke and comorbid psychological distress.

Stroke patients with co morbid mental illness have more outpatient visits and withdraw from family and community activities more due to psychological symptoms than stroke patients that are not suffering from comorbid mental illness. Better stroke management can lead to increased family and community involvement and over all quality of life as a result.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Having a better understanding of psychological distress barriers to making healthy stroke self-management choices will have greater benefits and outweigh potential risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A preliminary chart review will be conducted for interested study participants to examine if they have been hospitalized for psychiatric reasons within the last 30 days and if they have a diagnosis of psychotic or bipolar disorder to ensure study eligibility. A waiver of consent and HIPAA authorization is requested to determine subject eligibility.

An additional waiver of HIPPA authorization is being requested for the entire study for the following reason: To reduce participant burden, verbal consent is being obtained for study participation (see request to waive written documentation of consent in J1a). Therefore, we request a waiver of the requirement for HIPPA authorization for study participation.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

The research involves no more than minimal risk to the participants because the waiver will not affect the rights and welfare of the potential participants as this knowledge will be gained from medical records which can be accessed widely by VA researchers and clinicians. The only information reviewed in the medical records is that which will have already been asked of the patients. The patient will also be informed the research staff will review their medical records for the inclusion/exclusion criterial only.

The examination will be limited to mental health diagnosis, coexisting medical conditions, hospitalization for psychiatric, substance and/or alcohol use within the last 30 days. This information would have already been shared with the patient. Also, the data will not be used for any clinical purposes but only to determine eligibility for the current study. The purpose of collecting information covered under U.S.C 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research."

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

The waiver or alteration will not adversely affect the rights and welfare of the subjects, because the waiver will not affect the privacy rights and welfare of the potential participants as this knowledge will be gained from a medical records which can be accessed widely by VA researchers. The medical records information reviewed by the research staff that has already been shared with the patients and does not include undisclosed health information. The medical records examination will be limited to mental health diagnosis, coexisting medical conditions, hospitalization for psychiatric within the last 30 days. This information would have already been shared with the patient. Also, the data will not be used for any clinical purposes but only to determine eligibility for the current study.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

The research could not practicably be carried out without the waiver or alteration and without access to and use of the requested information, because conducting this initial medical chart investigation is essential to the research project. After experiencing a stroke, Veterans can experience a varying level of psychological distress and may have pre-existing psychological distress. Our program is not suited for participants with severe psychological distress. It would not be feasible to rely solely use the statements of the participant to gauge inclusion and exclusion criteria given patients with prior psychological distress may be more focused on the physical aspects of their stroke rather than their prior psychological symptoms. A greater focus on their physical changes may impact accurate recall of past information.

Describe how the research could not practicably be carried out without using the collected identifiable biospecimens in an identifiable format.

NA

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

An adequate plan exists in order to protect health information identifiers from improper use and disclosure, because all gathered PHI for potential participants will be stored in a locked file cabinet in a locked data storage room behind the VA firewall. No one outside of the PI, PI's research coordinator, Baylor College of Medicine Institutional Review Board members, VA Research and Development office and research compliance officers will have access to the data or limited PHI information.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

An adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so), because the information will be de-identified during the data entry process. The de-identified information will be used during all statistical analysis. The de-identified data will be stored in an encrypted file on the VA server. All of the identifiable and de-identified data (VA consent and HIPPA forms and audio files) will be properly destroyed immediately at the conclusion of the research project using VA established regulations. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule, because all gathered PHI for potential participants will be stored in a locked file cabinet in a locked data storage room behind the VA firewall. No one outside of the PI, PI's research coordinator, Baylor College of Medicine Institutional Review Board members, VA Research and Development office and research compliance officers will have access to the data or limited PHI information

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

Yes

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Other:

No

Will additional pertinent information be provided to subjects after participation?

No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.

Providing participants additional pertinent information after participation is not appropriate, because this information has already been shared with the participant by other clinicians. All additional information gained from the additional assessments and semi-structured interviews will be provided by the patient. Thus, there will not be any new information gained that the participant will not already know or have provided

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

We are requesting permission to verbally consent patient participants to this study by telephone. Given the treatment and research assessments are non-invasive in nature and almost exclusively involve monitoring and assessment of patient functioning, we have established telephone-based contact methods to decrease participant burden. To further improve this process, we are requesting to verbally consent participants to afford us greater opportunities to increase our outreach to patients and decrease participant burden . Patients will be initially introduced to the study and screened by telephone. If the initial screen indicates the patient may be eligible for the study, the patient will be mailed detailed information about the study procedures and an informed consent document (without signature lines) for their review. The study coordinator or other research staff will then follow up with the patient by telephone. Telephone consent will occur before administering baseline measures. Our protections for confidentiality are described below. The telephone screening will be conducted using a structured script (attached in section S).

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Patients receiving care in the inpatient stroke unit and the outpatient stroke clinic at the MEDVAMC will be targeted for treatment. Recruitment will take place based on referrals via the attending physical and nurses in the inpatient and outpatient stroke clinics at the MEDVAMC. The study coordinator will contact potential participants by mail or by phone. During this initial contact, a recruitment letter will be read to all potential subjects. A copy of the letter is available in section S. The letter will provide an overview of the study. Interested participants undergo an initial in person or telephone screening in order to determine eligibility. Participants who meet the inclusion criteria will then be provided with a hard copy of the consent and HIPPA form to be reviewed with study coordinator in person or via phone. The baseline assessment will be conducted after telephone consent has been obtained, and will last approximately 1 hour. After the verbal consent has been obtained the study staff will also assist with setting up video telehealth app and or review telephone usage, if applicable, and answer any additional questions. The baseline forms will gather demographic data such as age, gender, ethnicity, race, education, marital status, and employment. Participants will be asked about medications, other therapies, and hospitalizations. Additional assessments will measure mental health diagnosis and symptom severity. Participants who do not meet the inclusion criteria but demonstrate a need or ask for additional services will be referred for VA and community based mental health care services.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?
No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
Yes

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
The physical research data will be stored in a locked cabinet located at HSR&D CoE located at the Nabisco Building, 2450 Holcombe Boulevard, Suite O1Y, Houston, TX (Rm 121). No data will eave the MEDVAMC.

How will such physical research data be secured?

All forms of original data collected from this study will be stored in the VA Health Services Research and Development Center of Excellence (HSR&D C0E) which meets VA and BCM security requirements. These data will be stored in a locked cabinet located at HSR&D CoE located at the Nabisco Building, 2450 Holcombe Boulevard, Suite O1Y, Houston, TX (Rm 121). These data are stored behind 3 locked doors and to minimize risk to confidentiality, all data, including paper/pencil measures, will be labeled with participant numbers and only study personnel and members of the Data Monitoring and Safety Board will have access to these data. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

At what institution will the electronic research data be kept?

All electronic de-identified research data will be kept on a secure server of the MEDVAMC (VA server at the VA Health Services Research and Development Center of Excellence (HSR&D C0E) which meets VA and BCM security requirements. Data will be maintained on the secure servers of the HSR&D CoE located at the Nabisco Building, 2450 Holcombe Boulevard, Suite OIY, Houston, TX. During business and non-business hours, access to the server is behind locked doors. The server is backed up automatically each night. Data will be stored in folders on the M drive (M:RESEARCH/IMWHOLE/H43730) and only the research study staff will be given permission (requiring a logon and password) to access these folders. Results that are presented for publication will be reported in aggregate form, and therefore will not contain individual identifying information. No data will leave the MEDVAMC.

Such electronic research data will be secured via BCM IT Services - provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):

Yes, (describe below): Data will be maintained on the secure servers of the HSR&D CoE located at the Nabisco Building, 2450 Holcombe Boulevard, Suite O1Y, Houston, TX. During business and non-business hours, access to the server is behind locked doors. The server is backed up automatically each night. Data including digitally encrypted audio recordings, will be stored in folders on the M drive (M:RESEARCH/IMWHOLE/H43730) and only the research study staff will be given permission (requiring a logon and password) to access these folders.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:

People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

No data will leave the MEDVAMC.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

There are no foreseeable issues with confidentiality.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

0.00

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

60

Distribution Plan:
Each participant in phase II and phase III will receive 20.00 for each assessment they complete (0/6/12 weeks).

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)
No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Billboard

Exact language of Advertisement:
People who have had a stroke often experience sadness and worry. Untreated or poorly managed sadness and/or worry can cause poor progress after having a stroke and cause people to spend less time exercising or being with their family and friends.

The overall goal of this program is to develop, refine, and see if the I'm Whole treatment for Veterans with stroke and sadness and worry helps improve your way of living.

If you have had a stroke in the past year and have sadness and/or worry and would like to receive additional strategies to help you perform better physically and socially then I'm Whole can help. If you are interested in hearing more about the program please contact:

Dr. Gina Evans Principal Investigator (713) 440 – 4459 2002 Holcombe Blvd.

Thank you for your time and welcome to the I'm Whole program!